***Preliminary Program***

*(February 27, 2020)*

# Cell Culture Engineering XVII

**April 26 – May 1, 2020**

**JW Marriott Starr Pass Tucson Resort**

**Tucson, Arizona, USA**

**Conference Chairs**

**Timothy Charlebois**

Pfizer, Inc., USA

**Jamey Young**

**Vanderbilt University, USA**

**Gargi Maheshwari**



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**Engineering Conferences International**

**32 Broadway, Suite 314 - New York, NY 10004, USA**

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**Sunday, April 26, 2020**

12:30 – 17:30 Poster set-up

14:00 – 16:45 Conference Check-In

14:30 – 15:30 Early Career Preconference Flash talks (10 x 5-min talks)

15:30 – 16:15 Early Career Preconference Icebreaker/ Networking

16:15 – 16:45 Coffee break

16:45 – 17:00 Welcome remarks

CCE Chairs and ECI Liaison

17:00 – 17:45 **Keynote 1**

**How Technology, Big Data, and Systems Approaches are Transforming**

**21st Century Healthcare**

**Leroy Hood**, SVP and Chief Scientific Officer, Providence St. Joseph Health; Chief Strategy Officer, Co-founder and Professor, Institute for Systems Biology

18:00 – 19:30 Dinner

19:30 – 21:30 **Poster Session (even-numbered posters)**   
Chairs: Karthik Jayapal, Janssen, USA

Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA

Olivier Henry, Polytechnique Montreal, Canada

Yao-Ming Huang, Eli Lilly & Co., USA

**Monday, April 27, 2020**

**Breakfast on own**

08:00 – 08:45 **Keynote 2**

**TBD**

**Michael Kamarck**, Ph.D., Chief Technology Officer, Vir Technology

**Session 1: Systems and Synthetic Biology for Improved Cell Culture**

**Performance**

Chairs: Bhanu Muluktula, Pfizer, USA

Nicole Borth, University of Natural Resources and Life Sciences, Vienna

08:45 – 08:50 Session introduction

08:50 – 09:15 **HCP proteomics identifies difficult to remove HCPs as a function of cell age**

Kelvin Lee, University of Delaware, USA

09:15 – 09:40 **Solving the problem of clonal diversity through pathway mediated design approaches**

Paul E. Gulde, Thermo Fisher Scientific, USA

09:40 – 09:45 **Maximizing mAb galactosylation: Simultaneous removal of metabolic and cellular machinery bottlenecks**

Itzcoatl Gomez, University College Dublin, Ireland

09:45 – 10:10 **Systems design of virus production through synthetic biology**

Wei-Shou Hu, University of Minnesota, USA

10:10 – 10:40 Coffee Break

10:40 – 11:05 **Amino acid metabolism in CHO cells**

Maciek Antoniewicz, University of Delaware, USA

11:05 – 11:30 **Glycoengineering: A multidimensional challenge across different eukaryotic hosts**

Michael Betenbaugh, Johns Hopkins University, USA

11:30 – 11:35 **Mechanistic insights into N-glycosylation of recombinant proteins**

**produced in CHO cell fed-batch cultures through systems biology and**

**computational modeling**

Madhuresh Sumit, Pfizer Inc., USA

11:35 – 12:00 **Next-generation, feedback responsive cell factories for recombinant protein manufacturing**

Laura Segatori, Rice University, USA

12:00 – 13:30 Lunch

**Workshops (4 concurrent workshops)**

Chairs: Laura Palomares, IBT UNAM, Mexico

Anurag Khetan, Bristol-Myers Squibb, USA

**Monday, April 27, 2020 (continued)**

13:30 – 14:00 **Workshop 1**

**Advances and challenges with tech transfer, scale up and comparability**

Chairs: Diana Ritz, GSK, USA

Claudia Berdugo, Catalent, USA

Kelly Wiltberger, Biogen, USA

14:00 – 14:20 **Workshop 2**

**Actionable 'omics in cell culture and bioprocessing: Best practices and**

**opportunities**

Chairs:Henry Lin, Merck, USA

Paula Meleady, Dublin City University, Ireland

Nathan Lewis, University of California San Diego, USA

14:20 – 14:40 **Workshop 3**

**What does process and product characterization and biosimilar**

**development mean for process development of biologics?**

Chairs:Thomas Ryll, Immunogen, USA

Arti Narayanan, Genentech, USA

Jeff Yant, Amgen, USA

14:40 – 15:00 **Workshop 4**

**Opportunities and challenges bringing cell and gene therapies to patients**

**(and to market)**

Chairs:Andy Snowden, Kite, USA

Margarida Serra, IBET, Portugal

Liz Practico, Bluebird bio, USA

15:00 – 15:30 Coffee Break

**Session 2: Cell Line Development: Current State and Future Directions**

Chairs: Zhimei Du, Merck, USA

Mark Smales, University of Kent, United Kingdom

15:30 – 15:35 Session introduction

15:35 – 16:00 **What is in a phenotype?**

Nicole Borth, BOKU University of Natural Resources and Applied Life Sciences, Austria

16:00 – 16:25 **Chromosome instability and engineering for CHO and newly established Chinese hamster-derived cell line**

Takeshi Omasa, Osaka University, Japan

16:25 – 16:30 **Engineering of Chinese hamster ovary cell lipid metabolism results in an expanded ER and enhanced recombinant biotherapeutic protein production**

James Budge, University of Kent, United Kingdom

16:30 – 16:55 **Enhancing CHO cell performance via high-throughput screening and genetic engineering**

David Razafsky, MilliporeSigma, USA

**Monday, April 27, 2020 (continued)**

16:55 – 17:00 **Whole Genome CRISPR screening of CHO cells to improve bioproduction capabilities**

Bruno Fievet, Horizon Discovery, UK

17:00 – 17:25 **Integrated CHO cell line technologies for drug discovery, clinical development, and commercialization**

Gang Chen, Regeneron Pharmaceuticals, Inc., USA

17:30 – 18:00 Transition

18:00 – 19:30 Dinner

19:30 – 21:30 **Poster session (odd-numbered posters)**Chairs: Karthik Jayapal, Janssen, USA

Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA

Olivier Henry, Polytechnique Montreal, Canada

Yao-Ming Huang, Eli Lilly & Co., USA

**Tuesday, April 28, 2020**

**Breakfast on own**

**Session 3: Analysis and Control of Cell Culture-based Manufacturing**

Chairs: Marcella Yu, Boehringer Ingelheim, USA

Sarika Mehra, IIT Bombay, India

08:00 – 08:05 Session Introduction

08:05 – 08:30 **Nested control and advanced sensing for robust mAb glycan quality**

Anne Skaja Robinson, Carnegie Mellon University, USA

08:30 – 08:55 **Transforming molecule selection and process development through attribute focus and the deployment of high-performance computing tools**

Neeraj J. Agrawal, Amgen, USA

08:55 – 09:20 **Loss of cell viability is tracked by decreased cytoplasmic conductivity**

Michael Butler, NIBRT, Ireland

09:20 – 09:25 **Hybrid mechanistic-empirical modeling for biomanufacturing process optimization**

Conor O'Brien, University of Minnesota, USA

09:25 – 09:50 **Utilizing a web-based empirical modeling application to optimize amino acid concentrations in chemically-defined CHO cell culture media**

Taha Salim, Merck & Co., Inc., USA

09:50 – 10:20 Coffee Break

10:20 – 10:45 **Implementing PAT into manufacturing: Novel method to ensure pH comparability across sites and scales**

Christian Klinger, Roche Diagnostics GmbH, Germany

10:45 – 11:10 **Multi-omics BTI-MODEL platform aids QBD and incorporates automated glycan analysis**

Pauline M. Rudd, University College, Dublin, Ireland

11:10 – 11:35 **Debottlenecking mAb production by integrated systems biology approach of transcriptomics and genome-scale metabolic based metabolomics**

Seongkyu Yoon, University of Massachusetts Lowell, USA

11:35 – 11:40 **Achieving active control of cell culture performance with the aid of machine learning techniques**

John M. Schmitt, Lonza, USA

11:40 – 12:05 **Machine learning and advanced data analytics automating the exploitation of Raman spectroscopy: From micro-scale to large-scale operation**

Stephen Goldrick, University College London, United Kingdom

12:05 – 13:30 Lunch

**Tuesday, April 28, 2020 (continued)**

**Session 4: CCE for Cell-based Therapies**

Chairs: Chris Ramsborg, Bristol-Myers Squibb, USA

Krishnendu Roy, Georgia Institute of Technology, USA

13:30 – 13:35 Session Introduction

13:35 – 13:40 **Impact of heparin/collagen nanolayers on the expansion and immunophenotype of Mesenchymal stem cells**

Said Cifuentes, University of Puerto Rico, USA

13:40 – 13:45 **Functionalized microcarriers for enhanced CAR T cell manufacturing**

Nathan Dwarshuis**,** Georgia Institute of Technology, USA

13:45 – 14:10 **Development and implementation of an allogeneic cell therapy process platform**

Andrew Snowden, Kite Pharma Inc., USA

14:10 – 14:35 **Addressing bioprocess challenges for regulatory T-cell manufacturing**

James M. Piret, University of British Columbia, Canada

14:35 – 15:00 **Characterization of natural killer cell expansion through chronic stimulation with K562 cells for developing an off-the-shelf cellular therapy**

Samira Azarin, University of Minnesota, USA

15:00 – 15:25 **Process development and manufacturing for hematopoietic stem cell gene therapies**

Susan Abu-Absi, bluebird bio, USA

15:30 – 17:00 **Poster Session (even-numbered posters) / Coffee**

Chairs: Karthik Jayapal, Janssen, USA

Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA

Olivier Henry, Polytechnique Montreal, Canada

Yao-Ming Huang, Eli Lilly & Co., USA

17:00 Evening out with dinner at Old Tucson Studios

**Wednesday, April 29, 2020**

**Breakfast on own**

08:00 – 12:00 Networking time / Grab ‘n Go lunches

12:00 – 13:30 **Workshops (4 concurrent workshops)**

Chairs: Laura Palomares, IBT UNAM, Mexico

Anurag Khetan, Bristol-Myers Squibb, USA

**Workshop 5**

**Enable acceleration to the clinic and market**

Chairs: Nick Abu-Absi, Abbvie, USA

Shailendra Singh, Merck, USA

Ravali Raju, Pfizer, USA

**Workshop 6**

**Advances in cell engineering and alternate expression systems**

Chairs: Christina Alves, Biogen, USA

Susan Sharfstein, SUNY Polytechnic Institute, USA

Lasse Pedersen, Technical University of Denmark, Denmark

**Workshop 7**

**Industry 4.0: Big data, machine learning and artificial intelligence in cell culture**

Chairs: Seongkyu Yoon, University of Massachusetts, Lowell, USA

Madhuresh Sumit, Pfizer, USA

Kara Calhoun, Genentech, USA

**Workshop 8**

**Perfusion technologies: Challenges and opportunities**

Chairs: Leda Castilho, Federal University of Rio De Janeiro, Brazil

Jason Walther, Sanofi, USA

Sen Xu, Bristol-Myers Squibb Co., USA

13:45 – 14:30 **Martin Sinacore Award Lecture**

**Session 5: Continuing Challenges and Solutions in Biopharmaceutical Manufacturing: Scale-up, Scale-out, and Tech Transfer**

Chairs: Inn Yuk, Genentech, Inc., USA

Raghu Shivappa, Takeda, USA

14:30 – 14:35 Session Introduction

14:35 – 15:00 **Ensuring successful manufacturing scale-up via a comprehensive development and process transfer approach**

Kelly Wiltberger, Biogen, USA

15:00 – 15:25 **Challenges of an accelerated technology transfer and representative cell culture case studies**

Jonathan Cacciatore, Merck & Co., Inc., USA

15:25 – 15:50 **Making large scale processes transparent – Unraveling the impact of shear forces for scale-up and transfer**

Thomas Wucherpfennig, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

**Wednesday, April 29, 2020 (continued)**

15:50 – 16:15 **Ensuring comparability of drug substance through targeted process variation and media fingerprinting**

Kathryn Aron, Bristol-Myers Squibb, USA

16:15 – 16:20 **Characterization and improvement of shear related challenges in large-scale manufacturing TFF N-1 perfusion**

Alex Vaca, Biogen, USA

16:20 – 16:50 Coffee Break

16:50 – 17:15 **Off-gas analysis to enhance process monitoring, transfer and control**

Amy Nehring, Amgen, USA

17:15 – 17:40 **“Still or Sparkling?” - Scale-up and transfer of a process based on a particularly pCO2 sensitive cell line**

Sven Markert, Roche Diagnostics GmbH, Germany

17:40 – 18:05 **Understanding the impact of high gas entrance velocity on CHO cell culture processes to improve process scale up**

Robin Luo, Boehringer Ingelheim Fremont Inc., USA

18:05 – 18:30 **Bioreactor controller modeling and metabolic flux analysis to ensure comparable biopharmaceutical processes during scale-up and intensification**

Robert Balcarcel, Bayer U.S. LLC, USA

18:30 – 18:35 **Every patient, every time --- even for industry-neglected diseases**

Matthew Croughan, Tahoe Biotechnology Institute, USA

18:35 – 20:00 Dinner

20:00 – 21:30 **Poster Session (odd-numbered posters) / Social Hour**

Chairs: Karthik Jayapal, Janssen, USA

Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA

Olivier Henry, Polytechnique Montreal, Canada

Yao-Ming Huang, Eli Lilly & Co., USA

**Thursday, April 30, 2020**

**Breakfast on own**

08:00 – 08:45 **Keynote 3**

**Human Gene Therapy – Principles, History, State of the Art, Challenges and Approaches**

**Guangping Gao**, Ph.D., Professor, Department of Microbiology and

Physiological Systems; Director Gene Therapy Center & Viral Vector Core, University of Massachusetts Medical School

**Session 6: CCE for Gene therapy and emerging modalities**

Chairs: Scott Estes, Codiak Biosciences, USA

Jennifer Maynard, University of Texas-Austin, USA

08:45 – 08:50 Session Introduction

08:50 – 08:55 **Development of high cell density fed-batch culture for production of lentiviral vectors at high titer**

Chun Fang Shen, National Research Council of Canada, Canada

08:55 – 09:00 **The development and scale-up of an upstream process for manufacturing exosomes**

Joon Chong Yee, Codiak Bioscience, USA

09:00 – 09:25 **Intensified viral vaccine production: Towards a cell culture-based platform for perfusion mode cultivation**

Udo Reichl, MPI Magdeburg, Germany

09:25 – 09:50 **Process development for a red cell therapy: Producing a cell therapy without a nucleus**

Alan Gilbert, Rubius Therapeutics, USA

09:50 – 10:15 **Exosomes as delivery vehicles for RNA based therapeutics**

Kerstin Otte, University of Applied Sciences Biberach, Germany

10:15 – 10:45 Coffee Break

10:45 – 11:10 **Cell culture strategies to elevate recombinant adeno-associated virus production capacity in HEK293 cells**

Chia Chu, Pfizer, USA

11:10 – 11:35 **Dialing-in potency and high productivity for AAV production**

Peter Slade, Voyager Therapeutics, USA

11:35 – 12:00 **A novel AAV production process using suspension PCL cultivation**

Jenny Shupe, Biogen, USA

12:00 – 13:30 Lunch

**Thursday, April 30, 2020 (continued)**

**Session 7: Cell Culture for Integrated and Continuous Bioprocessing**

Chairs: Massimo Morbidelli, ETH Zurich, Switzerland

Chetan T. Goudar, Amgen, USA

13:30 – 13:35 Session Introduction

13:35 – 13:40 **Assessment of Ebri Breez biosystem microfluidic device as a scale down model for dynamic high-intensity, low-volume perfusion process (HILVOP)** Ana Maria Ovalle, Pfizer Inc., USA

13:40 – 13:45 **Commercial scale N-1 perfusion: Opportunities and challenges,**

Daniel Karst, Biogen, Switzerland

13:45 – 14:10 **Marching toward implementation of an integrated continuous biomanufacturing process: Turning fun into reality**

Marcella Yu, Boehringer Ingelheim Inc., USA

14:10 – 14:35 **Seed train intensification by smart high cell density cryopreservation and N-1 perfusion processes using specialized expansion media**

Mona Bausch, Merck KGaA, Germany

14:35 – 15:00 **Characterization of steady state and non-steady state perfusion cultures for leveraging these two different perfusion platforms for biologics manufacturing**

Jack Huang, Merck & Co., USA

15:00 – 15:25 **Development and implementation of the next generation intensified monoclonal antibody manufacturing process**

Jianlin Xu, BMS, USA

15:30 – 16:00 Coffee Break

16:00 – 17:00 **CCE Award Lecture**

17:00 – 18:00 Panel Discussion

18:00 – 18:30 Break

18:30 – 19:30 Reception

19:30 – 21:30 Banquet

**Friday, May 1, 2020**

Departures